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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,546	10/29/1999	NICHOLAS P. EVERETT	INTERLINK-3.	8843

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EXAMINER	
MCGARRY, SEAN	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 03/22/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/431,546	Applicant(s) EVERETT ET AL.	
	Examiner Sean McGarry	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) 14-17,25-35 and 46-48 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13,18-24 and 36-45 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 29 October 1999 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: 3 .

DETAILED ACTION

Applicant's election with traverse of Group II in Paper No. 14 is acknowledged. The traversal is on the ground(s) that groups II V and VI should be regrouped since the inventions of Groups V and VI are utilized in the invention of Group II. This is not found persuasive because applicant has not provide and specific arguments for this assertion and does not provide any argument or present any evidence that the reasons for restriction, provided in the restriction requirement mailed 9/27/01, are improper. However, claims drawn to Group VI will be examined with the invention of group II. Claims 25 and 26 were clearly not intended to be included in Group II and will not be examined since claims 25 and 26 are clearly not drawn to the expression of a peptide since the claims are drawn to a conjugated and crosslinked peptides. The requirement is still deemed proper and is therefore made FINAL.

Claims 14-17, 25-35 and 46-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

Claims 1-13, and 18-24 are examined as they read on the subject matter elected.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is unclear since, for example, it is unclear wheteher the claim is intended to include "functional equivalents" or indolicidin as well as Rev4.

There is no antecedent basis for the specific peptides recited in claims 3 and 4. Perhaps applicant intended the claims to read "said functional equivalent"?

Claims 2-4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This objection to is made in view of the rejection under 35 U.S.C. 112, second paragraph above since one formula appears to be drawn to indolicidin.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 18-24 and 36-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant specification teaches chemical synthesis of Rev4, Indolicidin, Ser-Rev4, Rev4-C-Terminal fusion, Indolicidin F, and Indolicidin F-P (amide) in Examples 1-6. The specification discloses in Example 8, the stability of Rev4 to proteases in whole cell extract. Example 9 discloses that Rev4 can "confer on Magainin 2 a stability" in whole cell extracts. Example 10 discloses that REV4 protects casein from commercial proteases in *in vitro* assays. In example 13 Rev4-related peptides which contained amino acid extensions on either the n-terminus or C-terminus (SEQ ID NO:s 5 and 6) were shown to have protease inhibiting properties while those peptides related to indolicidin had no protective effect. The specification then teaches one in the art how to make transgenic plants that express Rev4. the specification then teaches that such transgenic plants have increased resistance to pathogens.

The specification does not show that indolicidin per se nor any peptide related thereto confers to a protein any resistance to a protease nor does the specification show that transgenic plants comprising a transgenic Rev4 confers to a protein any

resistance to a protease when the protein is applied to the plant or expressed by the plant.

It is unclear how the examples and guidance provided in the specification provide adequate support for the range of rev4 or indolicidin "functional equivalents. It is noted that the use of the term functional equivalent is a very broad limitation that does not require that the peptide of the invention have any structural properties of the disclosed rev4 or indolicidin. It is noted that the instant specification does not show that indolicidin has any protease protective properties and further demonstrates specifically that peptide related to indolicidin did not have such properties. Further it is noted that the formula relied upon to define indolicidin and rev4 functional equivalents are so broad as to embrace Magainins (See US 5,424,395, columns 7 and 8, for example) which are purported to be protected from protease by the instant invention. It is applicants' position that Maiganins confer protection from proteases as the specific Rev4 examples in the instant specification do? is noted that the instant specification provides no guidance for one in the art what specific structures or sequences of Rev4 impart the protection from proteases and it was those peptides that contained additional amino acid on the C-terminus or N-terminus of Rev4 that maintained the ability to protect from proteases and the peptides that had modifications within the rev4 or indolicidin sequence that were even shown in the instant specification to not have protective properties. Staubitz et al have shown that, even after applicant filing date, it is not predictable what properties of indolicidin or reverse peptides will be changed by modifications of their core sequences [Staubitz et al Journal of Peptide Science Vol.

7:552-564, 2001]. The instant specification has not shown by example the protection of proteins applied to a plant or plant part by the expression of a Rev4 or indolicidin based peptide on or by the plant. Applicant appear to admit, at page 2 for example, and Mourgues et al [TIBTECH Vol. 16:203-210, 5/98] appear to assert, that the expression of exogenous protein in plant do not typically have the expected properties. Applicant has shown that proteins mixed in an in vitro environment, apparently devoid of any other plant material, were protected, but it is unclear how such an example correlates to the protection of a protein in/and or on a plant or plant part where the biological environment is very different than that where the specific examples were tested. An intact pant is most compartmentalized and the artificial conditions used in the instant examples, of course is not. An intact plant is a dynamic environment with many protein interactions, for example, where the artificial conditions used in the instant examples is static. A plant environment contains many variable which differ from plant to plant, from plant part to plant part, from plant tissue to tissue, and from cell to cell, for example. The example provided does not account for, what concentrations would need be expressed in a plant to confer protection to a particular peptide, and how does that peptide find that specific protein desired to be protected from all those in the plant environment, for example. Will the expressed protein protect all proteins in a plant, even those that need to be degraded for plant viability?

Since the art is unpredictable, the specification does not provide adequate guidance, and the specification fails to provide examples that correlate with the routine practice of the invention in view of the teachings of the specification, and since one in

the art would need to engage in undue trial and error experimentation to overcome the concerns above to practice the instant invention, the instant invention is not supported by an enabling specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM
March 21, 2002

SEAN McGARRY
PRIMARY EXAMINER